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| 10/784,900 | 02/24/2004 | Eugene R. Cooper | 029318-1003 | 1015 |
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| Elan Drug Delivery, Inc. c/o Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007-5109 | | | TRAN, SUSAN T | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 08/17/10 have been fully considered but they are not persuasive.

Applicant argues that Struengmann fails to fairly teach or suggest numerous other claim limitations, including the specific particle size. Struengmann fails to teach the specific surface stabilizers, their structural relationship to the particles, and that they are free of intermolecular cross-linkages. Thus, to combine the references as proposed in the rejection (to simply render the particles of Struengmann in the size of Liversidge) is not a straight-forward exercise as set forth by the rejection. For even if a person of ordinary skill in the art were to do this, (reduce the particles of meloxicam in Struengmann to the claimed range), Struengmann still fails to teach the specific surface stabilizers, their structural relationship to the particles, and that they are free of intennolecular cross-linkages.

Applicant further argues that Liversidge may fairly teach or suggest reduction in particle size to obtain higher bioavailability, but there is no reason for one skilled in the art to do this to the meloxicam of Struengmann because Struengmann already employs techniques to improve solubility and bioavailability. Struengmann discloses a solution for improving solubility and bioavailability "by mixing meloxicam with special additives" rather than by reducing the particle size to the nanoparticulate range. The special additives include surfactants, co-solvents, hydrotropic agents, alkalizing agents, cyclodextrins, hydrocolloids and polymers. See page 3, lines 4-16. There is no

suggestion by Struengmann that its methods for improving dissolution and bioavailability are in anyway insufficient and 1) would benefit by further reduction in particles size in view of Liversidge, and/or 2) would be possible using the techniques described in Liversidge.

However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Struengmann teaches co-micronized the active agent and the surfactant. Hence, the burden is shifted to applicant to show that the surfactant taught in Struengmann does not associate with the surface of the active nanoparticles. Further, Struengmann is cited in combination with the Liversidge patent, which teaches the association of surface modifier on the surface of the active drug, and the adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages (page 6, lines 25-31). It is noted that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

Applicant argues that the Examiner points out that "Liversidge teaches a process suitable for a wide variety of NSAIDs including oxicam" (final Office Action, page 7, lines 11-12). In order to advance prosecution, Applicants preemptively rebut a rejection in which Liversidge is used as the primary reference where one might state that it would be obvious to select the meloxicam of Struengmann in the process of Liversidge. Liversidge fails to expressly state meloxicam as an exemplary NSAID. Liversidge does disclose many exemplary NSAIDs at page 4, line 16, through page 5, line 4, and oxicam is one of the exemplified subgenus. Pursuant to MPEP 2144.08, the prior-art teaching of a genus does not necessarily renders the claimed species obvious. See the discussion submitted in the response filed on June 29, 2009, pages 31-32. Moreover, Liversidge discloses numerous surface modifiers at page 5, line 10, through page 6, line 24. In the absence of any teaching or fair suggestion from the cited reference, one skilled in the art would not have considered it obvious to select polyvinylpyrrolidone and sodium deoxycholate as the surface stabilizers, to obtain the claimed invention prescribed by claims 1 and 50.

However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Liversidge teaches a method for preparing a delivery system

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useful for a wide variety of active agents that include an NSAID. Struengmann teaches the desirability for preparing a delivery device that is useful for the delivery of an NSAID.

Accordingly, for at least the above reasons, the 103(a) rejections of record are maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/S. Tran/
Primary Examiner, Art Unit 1615